Overview of the Global Regulatory Status of Triclosan and Triclocarban

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Focus

- Review by numerous regulatory programs around the world at multiple levels
- Multiple regulatory vehicles
  - Pre-market (use-specific):
    - Pesticide approvals
    - Drug approvals
    - Cosmetic approvals
  - Post-market (chemical-specific):
    - National existing chemical programs
    - Governmental scientific reviews
- Risk/safety assessment v. hazard screening

Triclocarban: U.S. - FDA

- Regulated by FDA for use in OTC drugs
- FDA safety assessments (for human use)
  - Included in Tentative Final Monographs for Topical Antimicrobial Drug Products
  - "…recognized as safe for OTC daily topical use in a concentration of 1.5 percent…" (Fed. Reg. June 17, 1994)

Triclocarban: U.S. - EPA

- Sponsored by SDA-managed consortium under EPA HPV program in 1999
- Test plan submitted in December 2002

  (http://www.epa.gov/hpv/pubs/summaries/tricloca/c14186tc.htm)
- Plan revised in July 2006
- EPA issues hazard characterization in March 2008

(http://www.epa.gov/hpvis/hazchar/101202_Triclocarban_HC_INTERIM_March%202008.pdf)

Triclocarban: U.S. - EPA, cont.

- Test plan: 102 Robust Study Summaries (Complete SIDS data set)
- Hazard characterization (EPA)
  - No data gaps
  - Did not increase incidence of tumors
  - Potential health hazard moderate (lowest NOAEL 25 mg/kg-bw/day)
  - Potential hazard to aquatic organisms

Triclocarban: U.S. - EPA, cont.

- Considerations related to risk assessment:
  - Human Health
    - No safety issues with primary consumer exposure (use)
    - Minimal secondary consumer exposure
  - Environmental:
    - Low levels found in water streams; frequent monitoring; low risk to the aquatic environment
    - High removal in WWTPs via biosolids (55% land applied, 45% land-filled or incinerated)
    - Low bioavailability in biosolids-amended soil

Triclocarban: Canada

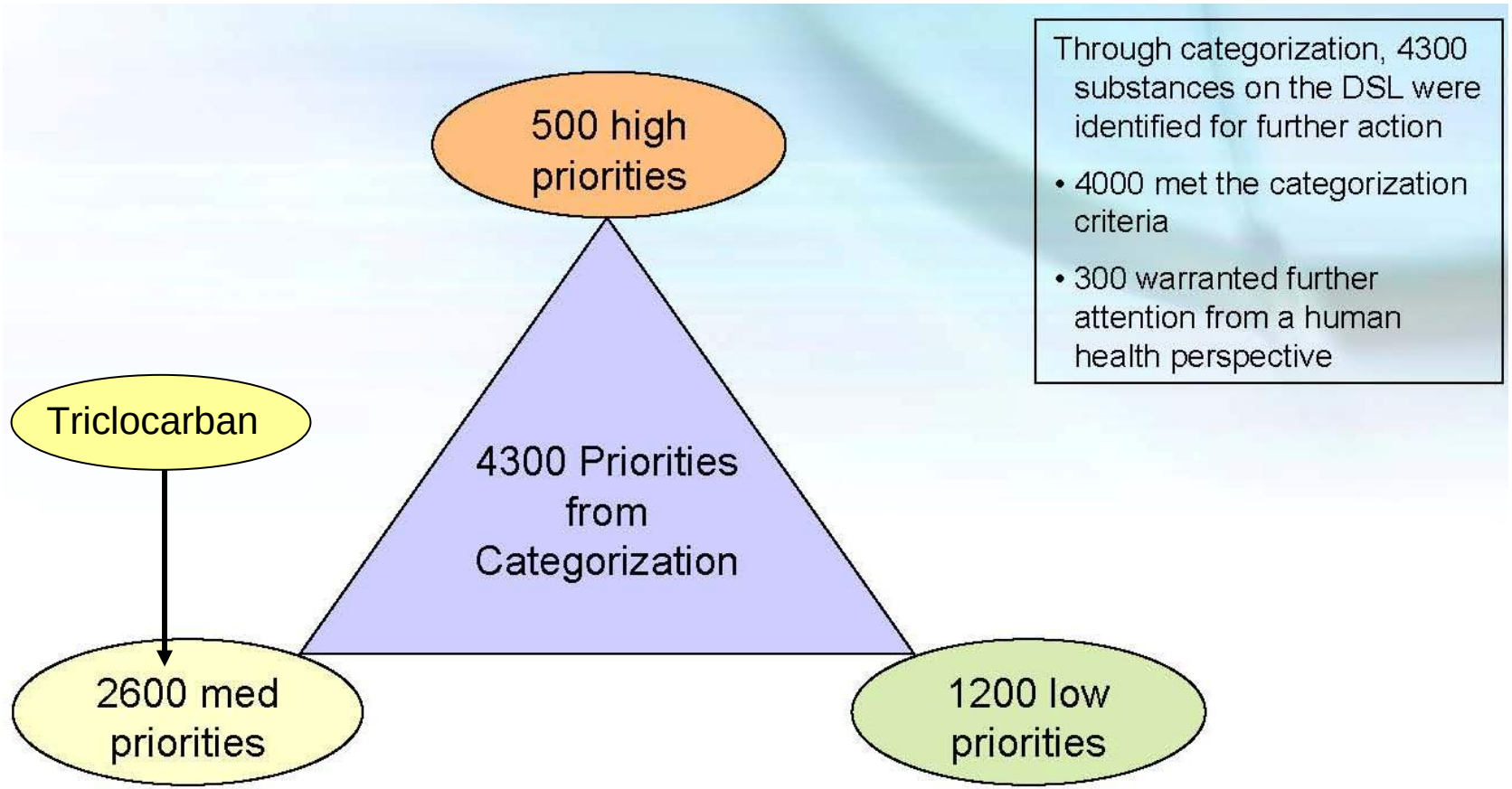
- Drug use approvals:
  - Antiseptic skin cleansers (hand soap)
  - Dental agents (toothpaste)
- Cosmetic use approval

Triclocarban: Canada, cont.

- Categorized Domestic Substances List chemicals (23,000) for further evaluation
- Met categorization criteria
  - Human health: **No**
  - Persistence: **Yes**
  - Bioaccumulation: **No**
  - Inherent Toxicity: **Yes**

    (to aquatic organisms)

Triclocarban: Canada, cont.



Triclocarban: European Union

- Approved as preservative for cosmetics with a max. permissible concentration of 0.2% (EU Directive 76/768/EEC)
- Approved at higher concentrations for purposes other than preservative of cosmetic agents, the purpose should be clearly defined by product labeling

Triclocarban: EU, cont.

- Scientific Committee on Consumer Products (SCCP) – June 2005
  - Assessed human health risks
    - “acceptable human safety profile for use in personal cleansing products”
    - High Margin of Safety (human) for current uses

Triclocarban: Switzerland, Japan

- Switzerland: Approved for cosmetics at these maximum usage concentrations:
  - 0.2% if in contact with mucous membranes
  - 0.5% if remain on skin (leave-on)
  - 2% if removed after brief use (rinse-off)
- Japan
  - Listed in Principles of Cosmetics Licensing with a maximum concentration of 0.3%

Triclosan: U.S. - FDA

- Regulated by FDA for use in drugs, cosmetics and medical devices
- Safety assessment by FDA for human use:
  - Included in two tentative final monographs for Topical Antimicrobial Drug Products
  - Approved under NDA as oral care drug product (toothpaste) to prevent gingivitis
  - Approved for use in medical devices (sutures, dental cement and prophylactic dental paste)

Triclosan: U.S. - EPA

- Regulated as a material preservative (pesticide) by EPA (FIFRA)
  - First registered in 1969
  - May 2008 Draft Reregistration Eligibility Decision (RED)
- RED Risk assessment
  - “Not Likely to be Carcinogenic to Humans” (CARC)
  - “…the aggregate [human] risks to triclosan from all uses (EPA and FDA) do not trigger a risk of concern.”
    - Based on human biomonitoring data for triclosan from NHANES
    - High Margin of Exposure (MOE; >100)
  - Environmental: Levels of concern were not exceeded for fish
    - Used occurrence data to estimate environmental exposure
    - PEC does not indicate any concerns for algae

Triclosan: Canada

- Drug use approvals:
  - Antiseptic skin cleansers (hand soap)
  - Dental agents (toothpaste)
- Cosmetic use approval
- Registered for pesticide (material preservative) uses
- Medium priority chemical under DSL screening

Triclosan: European Union

- Approved in 1989; published in Cosmetics Dir.
- Notified under Biocidal Products Directive for Disinfection/Biocidal Products & Preservatives
- In 2000, SCF concluded safe for food contact use where migration did not exceed 5 mg/kg
- Oct. 2006 SCCP concluded there is no evidence of resistance from cosmetic uses (safety dossier submitted and under review)

Triclosan: Australia

- Regulated for a variety of cosmetic, drug and pesticide uses
- Declared Priority Existing Chemical for full risk assessment by NICNAS in 2003 (in progress); Draft iteration (2008) consistent with US EPA evaluation
- Sponsor of triclosan under the OECD HPV Chemical program

Conclusions

- In most cases, triclosan and triclocarban are subject to pre-market government safety reviews
- There is extensive data available on the human and environmental safety of triclosan and triclocarban
- There has been global acceptance of the use of triclosan and triclocarban in numerous products
- Additional (redundant) post-market chemical evaluations have resulted in confirmation of the human and environmental safety of triclosan and triclocarban
- The ingredients have been used safely for more than 40 years across the globe